

PATENT  
Attorney Docket No. 402091/SKYEPHARMA

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

MISHRA et al.

Group Art Unit: 1617

Application No. 09/820,371

Examiner: E. Webman

Filed: March 26, 2001

For: INJECTABLE AQUEOUS DISPERSIONS  
OF PROPOFOL

*IDS and PTO  
1449 Forms as  
submitted on  
Jan. 24, 2004 in  
USSN 09/820,371*

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
Washington, D.C. 20231

Pursuant to 37 CFR 1.97 and 1.98, the references listed on the enclosed Form PTO-1449 and/or Substitute Form PTO-1449 ("Form 1449") are submitted for consideration by the Examiner in the examination of the above-identified patent application.

The full consideration of the references in their entirety by the Examiner is respectfully requested and encouraged. Also, it is respectfully requested that the references be entered into the record of the present application and that the Examiner place his or her initials in the appropriate area on the enclosed Form 1449, thereby indicating the Examiner's consideration of each of the references.

The submission of the references listed on the Form 1449 is for the purpose of providing a complete record and is not a concession that the references listed thereon are prior art to the invention claimed in the patent application. The right is expressly reserved to establish an invention date earlier than the above-identified filing date in order to remove any reference submitted herewith as prior art should it be deemed appropriate to do so.

Further, the submission of the references is not to be taken as a concession that any reference represents art that is relevant or analogous to the claimed invention. Accordingly, the right to argue that any reference is not properly within the scope of prior art relevant to an examination of the claims in the above-identified application is also expressly reserved.

The Information Disclosure Statement is being filed:

- ☐ within any one of the following time periods: (a) within three months of the filing date of a national application other than a continued prosecution application under 37 CFR 1.53(d); (b) within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 of an international application; (c) before the mailing date of a first Office Action on the merits; or (d) before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

- ☒ **after (a), (b), (c) or (d) above, but before the mailing date of a final action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an action that otherwise closes prosecution in the application, and includes *one* of:**
- ☐ the Statement under 37 CFR 1.97(e) (see "Statement under 37 CFR 1.97(e)" below).
- or*
- ☒ the fee of \$180 set forth in 37 CFR 1.17(p) (see "Fees" below).
- ☐ **after the mailing date of a final action under 37 CFR 1.113 or a Notice of Allowance under 37 CFR 1.311, or an action that otherwise closes prosecution in the application, and on or before payment of the issue fee, and includes the Statement under 37 CFR 1.97(e) (see "Statement under 37 CFR 1.97(e)" below), and the fee of \$180 as set forth in 37 CFR 1.17(p) (see "Fees" below).**
- ☐ **after the mailing date of a Notice of Allowance under 37 CFR 1.311, and on or before payment of the issue fee, and *within* thirty days of receiving each item of information contained in the Information Disclosure Statement, and includes the Statement under 37 CFR 1.704(d) (see "Statement under 37 CFR 1.704(d)" below), and the fee of \$180 as set forth in 37 CFR 1.17(p) (see "Fees" below).**

NOTE: This is for original applications except applications for a design patent, filed on or after May 29, 2000, wherein a paper containing only an Information Disclosure Statement in compliance with 37 CFR 1.97 and 1.98 is being filed.

#### Copies of the References

- ☐ Copies of the references listed on the enclosed Form 1449 are enclosed herewith. Attached to each reference not in the English language is a concise explanation of the relevance pursuant to 37 CFR 1.98(a)(3). An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of the relevance pursuant to 37 CFR 1.98(a)(3).
- ☐ A copy of the foreign search report is enclosed herewith.
- ☒ The references listed on the enclosed Form 1449 were previously identified in the parent application(s) of the present application, and copies of the references were furnished at that time. Accordingly, additional copies of the references are not submitted herewith, so as not to burden the file with duplicate copies of references. The Examiner is respectfully requested to carefully review the references in accordance with the requirements set out in the Manual of Patent Examining Procedure. In accordance with 37 CFR 1.98(d), the details of the parent application(s) relied upon for an earlier filing date under 35 USC 120 in which copies of the references were previously furnished are set out below:

| U.S. APPLICATIONS |                  | Status ( <i>check one</i> ) |         |           |
|-------------------|------------------|-----------------------------|---------|-----------|
| U.S. APPLICATIONS | U.S. FILING DATE | PATENTED                    | PENDING | ABANDONED |
| 1. 09/376,487     | August 18, 1999  |                             | X       |           |
| 2.                |                  |                             |         |           |
| 3.                |                  |                             |         |           |

**Statement under 37 CFR 1.97(e)**

- ☐ The **undersigned** hereby states that each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign patent application not more than three months prior to the filing of the Information Disclosure Statement.
- ☐ The **undersigned** hereby states that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the Information Disclosure Statement.

**Statement under 37 CFR 1.704(d)**

- ☐ The **undersigned** hereby states that each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and that this communication was not received by any individual designated in 37 CFR 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

**Fees**

- ☐ No fee is owed by the applicant(s).
- ☒ The **IDS Fee of \$180** under 37 CFR 1.17(p) is enclosed herewith.

**Method of Payment of Fees**

- ☐ Attached is a check in the amount of \$
- ☒ Charge Deposit Account No. 12-1216 in the amount of \$180.00. (A duplicate copy of this communication is enclosed for that purpose.)

**Authorization to Charge Additional Fees**

- ☒ If any additional fees are owed in connection with this communication, please charge Deposit Account No. 12-1216. (A duplicate copy of this communication is enclosed for that purpose.)

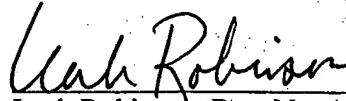
In re Appln. of Mishra et al.  
Application No. 09/820,371

**Instructions as to Overpayment**

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Credit Account No. 12-1216.  
Refund

Respectfully submitted,



Leah Robinson, Reg. No. 44,990  
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(202) 737-6776 (facsimile)

Date:  
LOR:ves

1/24/03

**INFORMATION DISCLOSURE  
CITATION**

ATTY. DOCKET NO.

SERIAL NO.

121-175

09/376,487

APPLICANT

MISHRA et al

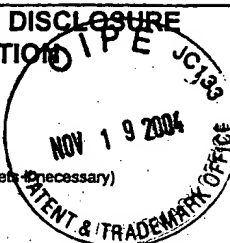
FILING DATE

GROUP

August 18, 1999

1617

(Use several sheets if necessary)



**U.S. PATENT DOCUMENTS**

| *EXAMINER<br>INITIAL | DOCUMENT NUMBER | DATE  | NAME            | CLASS | SUBCLASS | FILING DATE<br>IF APPROPRIATE |
|----------------------|-----------------|-------|-----------------|-------|----------|-------------------------------|
|                      | 5,589,508       | 12/96 | Schlotzer et al |       |          |                               |
|                      |                 |       |                 |       |          |                               |
|                      |                 |       |                 |       |          |                               |
|                      |                 |       |                 |       |          |                               |
|                      |                 |       |                 |       |          |                               |
|                      |                 |       |                 |       |          |                               |
|                      |                 |       |                 |       |          |                               |

**FOREIGN PATENT DOCUMENTS**

| DOCUMENT     | DATE | COUNTRY | CLASS | SUBCLASS | TRANSLATION<br>YES NO |
|--------------|------|---------|-------|----------|-----------------------|
| 0 770 387 A1 | 5/97 | Europe  |       |          |                       |
|              |      |         |       |          |                       |
|              |      |         |       |          |                       |
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|              |      |         |       |          |                       |
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**OTHER DOCUMENTS (including Author, Title, Date, Pertinent pages, etc.)**

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| *Examiner | Date Considered |
|-----------|-----------------|

Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

Form PTO-FB-A820 (Also PTO-1449)

**SERIAL NO.**

09/376,487

**APPLICANT**

MISHRA et al

FILING DATE

**GROUP**

1617

(Use several sheets if necessary)

## U.S. PATENT DOCUMENTS

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## FOREIGN PATENT DOCUMENTS

[illegible]

**OTHER DOCUMENTS** (including Author, Title, Date, Pertinent pages, etc.)

|           |  |   |
|-----------|--|---|
|           |  | COX EH et al., "Influence of different fat emulsion..." Pharmaceutical Research Vol. 15 No. 3, 3/98, pp 442-448 |
|           |  |   |
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|           |  |   |
| *Examiner |  | Date Considered   |

**\*Examiner**

**Date Considered**

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**SERIAL NO.**

09/376,487

APPLICANT

MISHRA et al

FILING DATE

**GROUP.**

August 18, 1999

1617

(Use several sheets if necessary)

## U.S. PATENT DOCUMENTS

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## FOREIGN PATENT DOCUMENTS

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**OTHER DOCUMENTS** (including Author, Title, Date, Pertinent pages, etc.)

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**\*Examiner**

Date Considered

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Form PTO-FB-A820 (Also PTO-1449)





Substitute for form 1449A/B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet

1

of

2

**Complete if Known**

|                        |                 |
|------------------------|-----------------|
| Application Number     | 9/376,487       |
| Filing Date            | August 18, 1999 |
| First Named Inventor   | MISHRA          |
| Group Art Unit         | 1617            |
| Examiner Name          | E. Webman       |
| Attorney Docket Number | 402090          |

**U.S. PATENT DOCUMENTS**

| Examiner<br>Initials | Doc. No. | U.S. Patent Document            |              | Name of Patentee or Applicant | Date of<br>Publication | Filing Date if<br>Appropriate |
|----------------------|----------|---------------------------------|--------------|-------------------------------|------------------------|-------------------------------|
|                      |          | Application or<br>Patent Number | Kind<br>Code |                               |                        |                               |
|                      | 1        | 4,056,635                       |              | Glen et al.                   | 11/1/1977              |                               |
|                      | 2        | 4,280,996                       |              | Okamoto et al.                | 7/28/1981              |                               |
|                      | 3        | 4,309,421                       |              | Ghyczy et al.                 | 1/5/1982               |                               |
|                      | 4        | 4,340,594                       |              | Mizushima et al.              | 7/20/1982              |                               |
|                      | 5        | 4,687,762                       |              | Fukushima et al.              | 8/18/1987              |                               |
|                      | 6        | 4,837,028                       |              | Allen                         | 6/6/1989               |                               |
|                      | 7        | 4,880,634                       |              | Speiser                       | 11/14/1989             |                               |
|                      | 8        | 4,895,726                       |              | Curtet et al.                 | 1/23/1990              |                               |
|                      | 9        | 5,023,087                       |              | Yau-Young                     | 6/11/1991              |                               |
|                      | 10       | 5,100,591                       |              | Leclef et al.                 | 3/31/1992              |                               |
|                      | 11       | 5,320,906                       |              | Eley et al.                   | 6/14/1994              |                               |
|                      | 12       | 5,527,537                       |              | Dietl                         | 6/18/1996              |                               |
|                      | 13       | 5,827,520                       |              | de Salvert                    | 10/27/1998             |                               |
|                      | 14       | 5,827,536                       |              | Laruelle                      | 10/27/1998             |                               |
|                      | 15       | 5,880,148                       |              | Edgar et al.                  | 3/9/1999               |                               |
|                      | 16       |                                 |              |                               |                        |                               |

**FOREIGN PATENT DOCUMENTS**

| Examiner<br>Initials | Doc. No. | Foreign Patent Document |                                 |              | Name of Patentee or Applicant | Date of<br>Publication | Translation |      |
|----------------------|----------|-------------------------|---------------------------------|--------------|-------------------------------|------------------------|-------------|------|
|                      |          | Office                  | Application or<br>Patent Number | Kind<br>Code |                               |                        | Yes         | No** |
|                      | 17       | DE                      | 25 13 797                       |              | ICI Ltd.                      | 10/9/975               |             | X+   |
|                      | 18       | DE                      | 29 38 807                       |              | Green Cross Corp.             | 11/13/1980             |             | X+   |
|                      | 19       | DE                      | 3421 468                        |              | Rentschler Arzenimittel       | 12/19/1985             |             | X+   |
|                      | 20       | EP                      | 052 322                         |              | Gersonde Klaus Prof Dr        | 5/26/1982              |             | X+   |
|                      | 21       | EP                      | 057 829                         |              | Fullard                       | 8/18/1982              |             |      |
|                      | 22       | EP                      | 272 091                         |              | Vestar, Inc.                  | 6/22/1988              |             |      |
|                      | 23       | EP                      | 330 532                         |              | Fournier Innovation Synergie  | 8/30/1989              |             | X+   |
|                      | 24       | EP                      | 391 369                         |              | Yissum Research Dev.          | 10/10/1990             |             |      |
|                      | 25       | EP                      | 418 153                         |              | Medgenix Group SA             | 3/20/1991              |             | X+   |
|                      | 26       | EP                      | 456 670                         |              | Braun Melsungen AG            | 11/21/1991             |             | X+   |
|                      | 27       | EP                      | 456 764                         |              | Braun Melsungen               | 11/21/1991             |             | X+   |
|                      | 28       | EP                      | 499 299                         |              | Sterling Winthrop Inc.        | 8/19/1992              |             |      |
|                      | 29       | EP                      | 535 567                         |              | Braun Melsungen AG            | 4/7/1993               |             | X+   |
|                      | 30       | EP                      | 570 829                         |              | Hans                          | 11/24/1993             |             | X+   |
|                      | 31       | EP                      | 601 618                         |              | Sterling Winthrop Inc.        | 6/15/1994              |             |      |
|                      | 32       | EP                      | 602 700                         |              | Sterling Winthrop Inc.        | 6/22/1994              |             |      |
|                      | 33       | EP                      | 724 877                         |              | Fournier Lab SA               | 8/7/1996               |             | X+   |
|                      | 34       | EP                      | 757 911                         |              | CLL Pharma                    | 2/12/1997              |             | X+   |
|                      | 35       | EP                      | 770 387                         |              | B. Braun Melsungen AG         | 5/2/1997               |             |      |
|                      | 36       | EP                      | 770 381                         |              | Oreal                         | 5/2/1997               |             | X+   |

Examiner Signature

Date Considered

\* A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).

+ An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 CFR 1.98(a)(3).

|  |   |    |   |                          |                 |
|--|---|----|---|--------------------------|-----------------|
| Substitute for form 1449A/B/PTO<br><br><b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br>(Use as many sheets as necessary) |   |    |   | <b>Complete if Known</b> |                 |
|  |   |    |   | Application Number       | 9/376,487       |
|  |   |    |   | Filing Date              | August 18, 1999 |
|  |   |    |   | First Named Inventor     | MISHRA          |
|  |   |    |   | Group Art Unit           | 1617            |
|  |   |    |   | Examiner Name            | E. Webman       |
| Sheet  | 2 | of | 2 | Attorney Docket Number   | 402090          |

| FOREIGN PATENT DOCUMENTS |          |                         |                                 |              |                                   |                        |             |      |
|--------------------------|----------|-------------------------|---------------------------------|--------------|-----------------------------------|------------------------|-------------|------|
| Examiner<br>Initials     | Doc. No. | Foreign Patent Document |                                 |              | Name of Patentee or Applicant     | Date of<br>Publication | Translation |      |
|                          |          | Office                  | Application or<br>Patent Number | Kind<br>Code |                                   |                        | Yes         | No** |
|                          | 37       | EP                      | 814 787                         |              | AstraZeneca AB                    | 1/7/1998               |             |      |
|                          | 38       | EP                      | 1 238 677                       |              | AstraZeneca AB                    | 9/11/2002              |             |      |
|                          | 39       | FR                      | 2 265 357                       |              | ICI Ltd.                          | 10/24/1975             |             | X+   |
|                          | 40       | FR                      | 2 617 047                       |              | Sanofi SA/Fournier Labs.          | 12/30/1988             |             | X+   |
|                          | 41       | JP                      | 55-141407                       |              | Nattermann A & CIE                | 11/5/1980              |             | X+   |
|                          | 42       | JP                      | 56-167616                       |              | Green Cross Corp.                 | 12/23/1981             |             | X+   |
|                          | 43       | JP                      | 60-208910                       |              | Green Cross Corp.                 | 10/21/85               |             | X+   |
|                          | 44       | JP                      | 63-502117                       |              |                                   | 8/18/1988              |             | X+   |
|                          | 45       | JP                      | 63-233915                       |              | Besutaa Res. Inc.                 | 9/29/1988              |             | X+   |
|                          | 46       | JP                      | 1-502590                        |              | Liposome Tech. Inc.               | 9/7/1989               |             | X+   |
|                          | 47       | HU                      | 211 580                         |              | Egis Gyogyszergy Rt.              | 12/28/1995             |             | X+   |
|                          | 48       | PCT                     | WO 85/00011                     |              | The University of Miami           | 1/3/1985               |             |      |
|                          | 49       | PCT                     | WO 87/04592                     |              | Liposome Tech. Inc.               | 8/13/1987              |             |      |
|                          | 50       | PCT                     | WO 91/04011                     |              | Riker Labs., Inc.                 | 4/4/1991               |             |      |
|                          | 51       | PCT                     | WO 93/19736                     |              | Kabi Pharmacia AB                 | 10/14/1993             |             |      |
|                          | 52       | PCT                     | WO 94/20072                     |              | Pharmacia AB                      | 9/15/1994              |             |      |
|                          | 53       | PCT                     | WO 96/01637                     |              | Astra Aktiebolag                  | 1/25/1996              |             |      |
|                          | 54       | PCT                     | WO 96/19064                     |              | Xcellenet, Inc.                   | 6/20/1996              |             |      |
|                          | 55       | PCT                     | WO 96/21439                     |              | Galephar P.R. Inc.                | 7/18/1996              |             |      |
|                          | 56       | PCT                     | WO 96/29064                     |              | Zeneca Ltd.                       | 9/26/1996              |             |      |
|                          | 57       | PCT                     | WO 97/10814                     |              | Vesifact AG                       | 3/27/1997              |             |      |
|                          | 58       | PCT                     | WO 97/14407                     |              | Research Triangle Pharmaceuticals | 4/24/1997              |             |      |
|                          | 59       | PCT                     | WO 98/53805                     |              | Saucy Ltd.                        | 12/3/1998              |             |      |
|                          | 60       | PCT                     | WO 99/39696                     |              | Gensia Sicor Inc.                 | 8/12/1999              |             |      |
|                          | 61       | PCT                     | WO 00/10531                     |              | RTP Pharma Inc.                   | 3/2/2000               |             |      |
|                          | 62       | PCT                     | WO 00/24376                     |              | Abbott Labs.                      | 5/4/2000               |             |      |
|                          | 63       | PCT                     | WO 00/54588                     |              | Krusz                             | 9/21/00                |             |      |
|                          | 64       | PCT                     | WO 00/59471                     |              | Baxter International, Inc.        | 10/12/2000             |             |      |
|                          | 65       | PCT                     | WO 00/59472                     |              | Baxter International, Inc.        | 10/12/2000             |             |      |
|                          | 66       | PCT                     | WO 00/78301                     |              | Kuhnli Pharm. Co. Ltd.            | 12/28/2000             |             |      |
|                          | 67       | PCT                     | WO 01/30372                     |              | BASF Aktiengesellschaft           | 5/3/2001               |             | X+   |
|                          | 68       | PCT                     | WO 02/21517                     |              | Zeon Corp.                        | 3/14/2002              |             | X+   |
|                          | 69       | UK                      | 2 046 094                       |              | A. Nattermann & Cie               | 11/12/1980             |             |      |
|                          | 70       | UK                      | 2 250 197                       |              | Egis Gyogyszergyar                | 6/3/1992               |             |      |
|                          | 71       | UK                      | 2 298 789                       |              | Zeneca Ltd.                       | 9/18/1996              |             |      |

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| Examiner Signature |  | Date Considered |  |
|--------------------|--|-----------------|--|

\* A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).

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|  |   |    |   |                          |                   |
|--|---|----|---|--------------------------|-------------------|
| Substitute for form 1449A/B/PTO<br><br><b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br>(Use as many sheets as necessary) |   |    |   | <b>Complete if Known</b> |                   |
|  |   |    |   | Application Number       | 09/376,487        |
|  |   |    |   | Filing Date              | August 18, 1999   |
|  |   |    |   | First Named Inventor     | MISHRA            |
|  |   |    |   | Group Art Unit           | 1617              |
|  |   |    |   | Examiner Name            | E. Webman         |
| Sheet  | 1 | of | 3 | Attorney Docket Number   | 402090/SKYEPhARMA |

| OTHER - NON PATENT LITERATURE DOCUMENTS |          |  |             |      |   |
|---|----------|--|-------------|------|---|
| Examiner<br>Initials                    | Doc. No. | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published. | Translation |      |   |
|   |          |  | Yes         | No** |   |
|   | 1        | "Diprivan 1% Injection," Physicians' Desk Reference, 1996, pp. 2833-39.  |             |      |   |
|   | 2        | "Diprivan 1% Injection," Physicians' Desk Reference, 1999, pp. 3411-18.  |             |      |   |
|   | 3        | Arduino, M.J. et al., "Microbial Growth and Endotoxin Production in the Intravenous Anesthetic Propofol", Infection Control and Hospital Epidemiology, Vol. 12, No. 9, September 1991, pp. 535-539.  |             |      |   |
|   | 4        | Babl et al., "New Formulations of Propofol in an LCT/MCT Emulsion: Approach to Reduce Pain on Injection", Eur. Hosp. Pharmacy, January 1995, Vol. 1, No. 1, pp. 15-21.   |             |      |   |
|   | 5        | Bangham et al., "Diffusion of Univalent Ions Across the Lamellae of Swollen Phospholipids," J. Mol. Biol., 1965, 13:238-251.   |             |      |   |
|   | 6        | Bennett et al., "Postoperative Infections Traced to Contamination of an Intravenous Anesthetic, Propofol", Vol. 333, No. 3, July 20, 1995, pp. 147-154.  |             |      |   |
|   | 7        | Benz et al., "Electrical Capacity of Black Lipid Films and of Lipid Bilayers made from Monolayers," Biochimica et Biophysica Acta, 1975, 394:323-334.  |             |      |   |
|   | 8        | Bergmann, Ludwig, Der Ultraschall, 5 Aufl., 1949, Struttgart, pp. 551-564 and 665-677.   |             |      | X |
|   | 9        | Bittman, Robert, "Sterol-Polyene Antibiotic Complexation: Probe of Membrane Structure," LIPIDS, Vol. 13, No. 10, pp. 686-691 (1978).   |             |      |   |
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| Examiner<br>Signature |  | Date<br>Considered |  |
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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| Filing Date            | August 18, 1999    |
| First Named Inventor   | MISHRA             |
| Group Art Unit         | 1617               |
| Examiner Name          | E. Webman          |
| Attorney Docket Number | 402090/SKYE PHARMA |

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|                        |                   |
|------------------------|-------------------|
| Application Number     | 09/376,487        |
| Filing Date            | August 18, 1999   |
| First Named Inventor   | MISHRA            |
| Group Art Unit         | 1617              |
| Examiner Name          | E. Webman         |
| Attorney Docket Number | 402090/SKYEPhARMA |

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| Attorney Docket Number | 402090/SKYE PHARMA |

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| Substitute for form 1449A/B/PTO<br><br><b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br>(Use as many sheets as necessary) |   |    | <b>Complete if Known</b> |                        |                    |
|  |   |    | Application Number       | 09/376,487             |                    |
|  |   |    | Filing Date              | August 18, 1999        |                    |
|  |   |    | First Named Inventor     | MISHRA                 |                    |
|  |   |    | Group Art Unit           | 1617                   |                    |
|  |   |    | Examiner Name            | E. Webman              |                    |
| Sheet  | 2 | of | 2                        | Attorney Docket Number | 402090/SKYE PHARMA |

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|                          |          | Office                  | Application or Patent Number | Kind Code |                               |                     | Yes         | No** |
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| Application Number     | 09/376,487         |
| Filing Date            | 8/18/99            |
| First Named Inventor   | Awadhesh K. Mishra |
| Group Art Unit         | 1617               |
| Examiner Name          | E. Webman          |
| Attorney Docket Number | 402090/SKYE PHARMA |

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\* References being submitted under separate cover



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|                        |                    |
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| Application Number     | 09/376,487         |
| Filing Date            | 8/18/99            |
| First Named Inventor   | Awadhesh K. Mishra |
| Group Art Unit         | 1617               |
| Examiner Name          | E. Webman          |
| Attorney Docket Number | 402090/SKYEPhARMA  |

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| Examiner<br>Initials | Doc. No. | U.S. Patent Document            |              | Name of Patentee or Applicant | Date of<br>Publication | Filing Date If<br>Appropriate |
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| Examiner Name          | E. Webman          |
| Attorney Docket Number | 402090/SKYEPhARMA  |

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| Examiner Name          | E. Webman          |
| Attorney Docket Number | 402090/SKYEPhARMA  |

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## **U.S. PATENT DOCUMENTS**

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|------------------------|--------------------|
| Application Number     | 09/376,487         |
| Filing Date            | 8/18/99            |
| First Named Inventor   | Awadhesh K. Mishra |
| Group Art Unit         | 1617               |
| Examiner Name          | E. Webman          |
| Attorney Docket Number | 402090/SKYEPhARMA  |

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| Sheet | 12 | of | 12 |
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## INFORMATION DISCLOSURE CITATION

ATTY. DOCKET NO.

121-175

APPLICANT

MISHRA et al

FILING DATE

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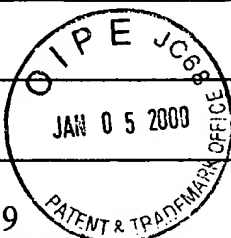
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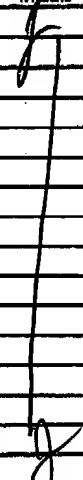
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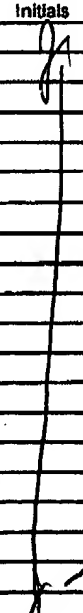
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|  |   |                          |                 |
| <b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b> |   | Application Number       | 9/376,487       |
|  |   | Filing Date              | August 18, 1999 |
|  |   | First Named Inventor     | MISHRA          |
|  |   | Group Art Unit           | 1617            |
|  |   | Examiner Name            | E. Webman       |
| (Use as many sheets as necessary)                        |   | Attorney Docket Number   | 402090          |
| Sheet  | 1 | of                       | 2               |

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Examiner Name E. Webman  
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|                      |          | Office                  | Application or<br>Patent Number | Kind<br>Code |                                   |                        | Yes         | No** |
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|                      | 38       | EP                      | 1 238 677                       |              | AstraZeneca AB                    | 9/11/2002              |             |      |
|                      | 39       | FR                      | 2 265 357                       |              | ICI Ltd.                          | 10/24/1975             |             | X+   |
|                      | 40       | FR                      | 2 617 047                       |              | Sanofi SA/Fournier Labs.          | 12/30/1988             |             | X+   |
|                      | 41       | JP                      | 55-141407                       |              | Nattermann A & CIE                | 11/5/1980              |             | X+   |
|                      | 42       | JP                      | 56-167616                       |              | Green Cross Corp.                 | 12/23/1981             |             | X+   |
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|                      | 45       | JP                      | 63-233916                       |              | Besutaa Res. Inc.                 | 9/29/1988              |             | X+   |
|                      | 46       | JP                      | 1-502590                        |              | Liposome Tech. Inc.               | 9/7/1989               |             | X+   |
|                      | 47       | HU                      | 211 580                         |              | Egis Gyogyszergyar Rt.            | 12/28/1995             |             | X+   |
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|                      | 66       | PCT                     | WO 00/78301                     |              | Kuhnli Pharm. Co. Ltd.            | 12/28/2000             |             |      |
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|                      | 68       | PCT                     | WO 02/21517                     |              | Zeon Corp.                        | 3/14/2002              |             | X+   |
|                      | 69       | UK                      | 2 046 094                       |              | A. Nattermann & Cie               | 11/12/1980             |             |      |
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|                      | 71       | UK                      | 2 298 789                       |              | Zeneca Ltd.                       | 9/18/1996              |             |      |

Examiner Signature

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Date Considered

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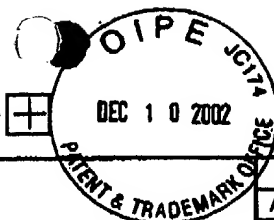
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| Substitute for form 1449A/B/PTO   |                        | <b>Complete if Known</b> |                 |
| <b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br>(Use as many sheets as necessary) |                        | Application Number       | 09/376,487      |
|   |                        | Filing Date              | August 18, 1999 |
|   |                        | First Named Inventor     | MISHRA          |
|   |                        | Group Art Unit           | 1617            |
|   |                        | Examiner Name            | E. Webman       |
| Sheet 1 of 3  | Attorney Docket Number | 402090/SKYE PHARMA       |                 |

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# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet **2** of **3**

**Complete if Known**

Application Number **09/376,487**  
 Filing Date **August 18, 1999**  
 First Named Inventor **MISHRA**  
 Group Art Unit **1617**  
 Examiner Name **E. Webman**  
 Attorney Docket Number **402090/SKYE PHARMA**

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| Examiner Initials | Doc. No. | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published. | Translation |     |
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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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|                        |                    |
|------------------------|--------------------|
| Application Number     | 09/376,487         |
| Filing Date            | August 18, 1999    |
| First Named Inventor   | MISHRA             |
| Group Art Unit         | 1617               |
| Examiner Name          | E. Webman          |
| Attorney Docket Number | 402090/SKYE PHARMA |

Sheet 3 of 3

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| Examiner<br>Initials | Doc. No. | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published. | Translation |      |
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| Examiner<br>Signature |  | Date<br>Considered | 6/04 |
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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Sheet

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of

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Application Number

09/376,487

Filing Date

August 18, 1999

First Named Inventor

MISHRA

Group Art Unit

1617

Examiner Name

E. Webman

Attorney Docket Number

402090/SKYE PHARMA

**U.S. PATENT DOCUMENTS**

| Examiner<br>Initials | Doc. No. | U.S. Patent Document            |              | Name of Patentee or Applicant | Date of<br>Publication | Filing Date If<br>Appropriate |
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Examiner Signature

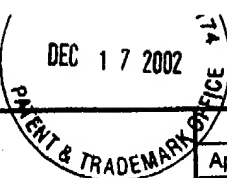
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Sheet 2 of 2

|                        |                    |
|------------------------|--------------------|
| Application Number     | 09/376,487         |
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| First Named Inventor   | MISHRA             |
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| Examiner Name          | E. Webman          |
| Attorney Docket Number | 402090/SKYE PHARMA |

## U.S. PATENT DOCUMENTS

| Examiner Initials | Doc. No. | U.S. Patent Document         |           | Name of Patentee or Applicant | Date of Publication | Filing Date If Appropriate |
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- \* A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).  
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